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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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MILLEN, WHITE, ZELANO & BRANIGAN, PC 2200 CLARENDON BLVD SUITE 1400 ARLINGTON, VA 22201			ROYDS, LESLIE A	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 10/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/774,697	COUCH ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12 September 2006</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-28 are presented for examination.

Applicant's Amendment filed July 26, 2006 has been received and entered into the present application. Accordingly, the specification at pages 6 and 32 has been amended. Applicant's Information Disclosure Statement (IDS) filed September 12, 2006 has also been received and entered into the application. As reflected by the attached, completed copy of form PTO/SB/08 a/b (one page total), the Examiner has considered the cited references.

Claims 1-28 remain pending and are under examination. Claims 20, 25 and 28 are amended.

Applicant's arguments, filed July 26, 2006, have been fully considered. Rejections and objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and objections are either reiterated or newly applied. They constitute the complete set of rejections and objections presently being applied to the instant application.

Objection to the Specification

Applicant's amendments to the specification at pages 6 and 32 have been noted, but insofar as Applicant has again failed to remove the hyperlink from the specification at page 32, line 23, the following objection remains proper and is maintained:

The disclosure remains objected to because it contains an embedded hyperlink and/or other form of browser-executable code at page 32, line 23. **Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code.** Please reference MPEP §608.01.

Claim Rejections - 35 USC § 112, Second Paragraph (New Grounds of Rejection)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-28 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. Please reference MPEP §2172.01.

While Applicant has claimed particular release characteristics of the pharmaceutical combination of present claim 1 or the amphetamine(s) to be administered as a part of the method of, for example, present claim 16, by the recitation of “each adapted for release such that the molar ratio of l-amphetamine to d-amphetamine released therefrom in a time period later in the day is higher than said ratio released therefrom in a time period earlier in the day” (claim 1) or “each adapted for release such that the molar ratio of the total amount of l-isomer to the total amount of d-isomer administered per day is greater than 1:3” (claim 16), it is clear that Applicant has omitted elements of the combination or the formulation of the amphetamine(s) that are essential to effect such a release profile. Applicant states the following at page 10, lines 11-22 and page 11, lines 31-32:

“The release profiles of amphetamine can be accomplished routinely with a wide variety of conventional formulations, e.g., with structures such as solids having an essentially homogeneous composition or multiple layers, beads, matrices, materials which provide osmotically driven delivery, compartmental delivery forms (e.g., transdermal patches, osmotic forms, etc.), and various combinations thereof (e.g., layers on beads, different bead compositions and configurations mixed together in a capsule or separately provided, different ratios of isomers in different compartments, e.g. of a patch, device, composition etc., any of which can be formulated for immediate, extended, delayed, etc. release. Formulations for achieving the foregoing dosing regimens are conventional. These can use immediate, controlled, sustained, extended, pulsatile, etc. technologies, alone or in combination to achieve the desired regimens [see page 10, lines 11-22]... Various polymeric materials can be used to achieve the desired type of pattern of release, e.g., immediate, sustained, delayed etc. release [see page 11, lines 31-32].”

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Applicant has provided various examples of pharmaceutical combination at pages 34-39 of the disclosure describing particular pharmaceutical combinations that are within the scope of Applicant's invention. However, because Applicant has not specifically claimed the vehicle, the components of the vehicle, the formulation or other additives that are relevant to establishing a pharmaceutical combination wherein more d-amphetamine is released immediately and more l-amphetamine is released later, the claims are considered to be incomplete.

Absent such limitations, the recitation of the release profile of the l-isomer and the d-isomer of the combination does not impart any physical or material property to the combination. As a result, the claims do not distinguish over a pharmaceutical combination simply comprising amphetamine in base and/or salt form. The release characteristics that Applicant has ascribed to such a composition are considered immaterial to the fact that amphetamine in base and/or salt form is required to be physically present in such a pharmaceutical combination. However, if Applicant intends to claim a particular pharmaceutical formulation of d- and l-amphetamine in which the d- and l-isomers are released at different times, then any elements considered essential to such a formulation, particularly the type of delivery system (i.e., immediate release capsule, bead formulation, multi-layer tablet, etc.), the components of such a delivery system (i.e., a particular enteric coating, solvent, carrier, etc.) or a polymer or equivalent that aids in the immediate release of d-amphetamine and delayed release of l-amphetamine, should be recited in the claims. Applicant is required to particularly point out and claim that which he regards as the invention; in light of the disclosure, it appears that Applicant has omitted physical and/or structural elements that are considered material to the composition in order to obtain the release characteristics as claimed.

Furthermore, it is noted that the limitation "each adapted for release" (claims 1 and 16) is not an active requirement of the pharmaceutical combination and reads upon a future "adaptation" of the l- and d-amphetamines to effect the release characteristics actually claimed. In other words, the claims as

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presently written do not require that the amphetamines already be formulated for such a release, but rather that the amphetamine components, at some later point, are prepared such that the claimed release profile is achieved.

Accordingly, the claims fail to reasonably apprise the skilled artisan of the subject matter for which Applicant is seeking protection and also fail to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and are, therefore, properly rejected.

For the purposes of examination, the claims will be examined insofar as they read upon the physical or material limitations of the combination (i.e., that l- and d-amphetamine be present in an effective amount in base and/or salt form) since, absent any physical or structural distinction of the composition of the present claims, the recitation of the release profile of the combination is a resultant function or intended use of the composition and is not a patentable distinction over the art.

Claim Rejections - 35 USC § 102 (New Grounds of Rejection)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11, 14-15 and 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Burnside et al. (U.S. Patent No. 6,322,819; 2001).

Burnside et al. teaches a multiple pulsed dose drug delivery system for administering amphetamine salts and mixtures thereof (col.3, lines 16-20), wherein the composition provides immediate release and enteric release (each pulsed type release) of one or more amphetamine salts and mixtures thereof. Burnside et al. teaches pharmaceutically active amphetamine salts, such as amphetamine base

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and all chemical and chiral derivatives and salts thereof (col.7, lines 48-55). Such a teaching meets the limitation of "base and/or salt form" (see present claim 1), since the reference clearly anticipates the use of base alone, base and salt, or salts alone, and within each any chemical or chiral derivatives of base, salt, or base and salt. Additionally, the teaching of amphetamine base and all chiral derivatives thereof meets the limitation of present claim 24, wherein the pharmaceutical combination contains l-isomer.

While the Examiner has considered the limitations recited in present claims 2-11 and 14-15, the recitation(s) of the release profile of the pharmaceutical combination fails to impart any physical or material properties to the combination that is not already present in the prior art of Burnside. Applicant is reminded that claims to compositions of matter are analyzed on the basis of their physical and structural characteristics. Recitations of function or, in the present case, release, of the claimed composition, in the absence of a physical or structural difference, do not patentably limit the composition.

In the instant case, each and every limitation of the present claims regarding the release profile of the composition has been fully considered to determine whether such limitations provide a physical or structural limitation to the overall generic structure of the claimed pharmaceutical combination, which they do not. Applicant has omitted the physical elements of the composition that result in the claimed release profile. In the absence of such elements, the claimed composition solely requires the physical presence of both d- and l-amphetamines, in base and/or salt form, in an effective amount. These physical requirements are met by the teachings of Burnside. Please reference, for example, MPEP §2111.02[R-3].

Applicant's attention is directed to MPEP §2112.01, which states:

"Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established...Products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable.

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Therefore, if the prior art teaches the identical chemical structure, the properties Applicant discloses and/or claims are necessarily present.”

Claims 1-16 and 27-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Patrick et al. (“Pharmacology of Methylphenidate, Amphetamine Enantiomers and Pemoline in Attention-Deficit Hyperactivity Disorder”, 1997; p.527-546).

Patrick et al. teaches dextroamphetamine and levoamphetamine mixed salts, marketed and sold under the brand name ADDERALL® in the treatment of attention deficit hyperactivity disorder (ADHD). Patrick et al. discloses that ADDERALL® is a combination product comprising dextroamphetamine saccharate, dextroamphetamine sulfate, racemic amphetamine aspartate and racemic amphetamine sulfate (page 537, col.2, last paragraph). Patrick et al. also teaches that the total free base equivalence in, for example, a 10 mg tablet is 6.3 mg, of which 81% is dextroamphetamine and 19% is levoamphetamine (see also page 537, col.2, last paragraph).

Furthermore, Patrick et al. further teaches that the recommended dosage for the treatment of ADHD is 5 mg once or twice per day (considered by the Examiner to meet the limitation of two separate oral dosage forms; see Table 3 at page 535 which states a table formulation of ADDERALL®) with incremental increases of 5 mg/week until optimal response is established; but generally not to excess 40 mg/day. Although the reference does not specifically teach a range of amphetamine between 1 and 200 mg/day (see present claim 12), Patrick et al. anticipates the range insofar as it reads upon a dose of amphetamine of 5-40 mg/day (see MPEP § 2131.01 regarding rejections under 35 U.S.C. § 102 of ranges).

While the Examiner has considered the limitations recited in present claims 2-11 and 14-15, the recitation(s) of the release profile of the pharmaceutical combination fails to impart any physical or material properties to the combination that is not already present in the prior art of Patrick. Applicant is

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reminded that claims to compositions of matter are analyzed on the basis of their physical and structural characteristics. Recitations of function or, in the present case, release, of the claimed composition, in the absence of a physical or structural difference, do not patentably limit the composition.

In the instant case, each and every limitation of the present claims regarding the release profile of the composition has been fully considered to determine whether such limitations provide a physical or structural limitation to the overall generic structure of the claimed pharmaceutical combination, which they do not. Applicant has omitted the physical elements of the composition that result in the claimed release profile. In the absence of such elements, the claimed composition solely requires the physical presence of both d- and l-amphetamines, in base and/or salt form, in an effective amount. These physical requirements are met by the teachings of Patrick. Please reference, for example, MPEP §2111.02[R-3].

Applicant's attention is directed to MPEP §2112.01, which states:

“Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established...Products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties Applicant discloses and/or claims are necessarily present.”

It is further noted that the recitation of the efficacy of the treatment method (see present claim 28) is also not considered to further limit the method steps of the claim from which it depends (see present claim 27). While such a limitation has been considered by the Examiner, it does not impart any additional limiting steps or processes to the method that are not already present in the method of treatment as disclosed by Patrick et al. Additionally, administration of the same combination to the same host for the same therapeutic purpose will inherently have the same effectiveness as compared to another pharmacotherapy, even if not explicitly stated in the reference.

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Claim Rejections - 35 USC § 103 (New Grounds of Rejection)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patrick et al. ("Pharmacology of Methylphenidate, Amphetamine Enantiomers and Pemoline in Attention-Deficit Hyperactivity Disorder", 1997; p.527-546) in view of Epstein et al. (WO 2002/039998; 23 May 2002), Burnside et al. (U.S. Patent No. 6,322,819; 2001), STN Registry file (Registry No. 156-34-3) and Tulloch et al. ("SLI381 (Adderall XR), a Two-Component, Extended Release Formulation of Mixed Amphetamine Salts: Bioavailability of Three Test Formulations and Comparison of Fasted, Fed and Sprinkled Administration", Pharmacotherapy, 2002;22(11):1405-1415).

The differences between the Patrick et al. reference and the presently claimed subject matter lie in that the reference does not teach:

(i) the total dose of amphetamine per day from 1-4 mg and 41-200 mg/day;

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(ii) the administration of a composition of the l- and d-isomers of amphetamine in a single staged-release, immediate release, pulse release and/or sustained or controlled release dosage forms; and

(iii) the administration of an amphetamine composition in two doses, the first having an l/d isomer ratio of about 1:3 or contains only d-isomer and the second dose having an l/d isomer ratio of greater than about 1:1 or contains l-isomer only.

However, the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains because of the following reasons:

(i) The determination of the optimum dosage regimen to treat ADHD with the presently claimed active amphetamine combination would have been a matter well within the purview of one of ordinary skill in the art. Such a determination would have been made in accordance with a variety of factors, such as the age, weight, sex, diet and medical condition of the patient, severity of the disease, the route of administration, pharmacological considerations, such as the activity, efficacy, pharmacokinetics and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized and whether the compound is administered as part of a drug combination. Thus, the dosage regimen that would have actually been employed would have varied widely and, in the absence of evidence to the contrary, the currently claimed specific dosage amounts are not seen to be inconsistent with the dosages that would have been determined by the skilled artisan. In addition, the amphetamine dosage is a result-effective variable, i.e., a variable that achieves a recognized result, and, therefore, the determination of the optimum of workable dosage range would be well within the practice of routine experimentation by the skilled artisan, absent factual evidence to the contrary, and, further, absent any evidence demonstrating a patentable difference between the compositions used and the criticality of the amount(s).

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Applicant's attention is further drawn to MPEP at §2144.05, which states, "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages." Although the present set of facts are drawn to mg/day dosages, the motivation as drawn from the MPEP at §2144.05 is nonetheless relevant.

(ii) Patrick et al. teaches a single dosage formulation containing both d-, l- and racemic amphetamine and amphetamine salts, but is silent as to the preparation of the combination of compounds in an immediate, pulse release and/or sustained or controlled release dosage forms. However, such formulations were well known in the art at the time of the invention (see, for example, Burnside et al., U.S. Patent No. 6,322,819; 2001). The use of such a dosage formulation as disclosed by Burnside et al. would have been *prima facie* obvious to the skilled artisan in order to effect the desired release profile of the drug and to sustain the therapeutic benefit to the patient over a longer period of time without the need for frequent dosing. Such a person would be motivated to do so in order to alter the release characteristics of the composition to enhance bioavailability and pharmacologic effect.

Furthermore, formulation of a composition containing d-, l- and racemic amphetamine as taught by Patrick et al. into a special release preparation (i.e., immediate, pulse, controlled or sustained release) would necessarily contain l-isomer and is, thus, not considered to be a difference between the presently claimed subject matter and the Patrick et al. reference in light of what was known in the art.

(iii) Epstein et al. provides teaching that the l-isomer of amphetamine demonstrated fewer addictive properties and had greater memory enhancing effects as compared to the d-isomer. Epstein et al. teaches, "In particular, we describe herein the use of pharmaceutical preparations for increasing long-term potentiation and/or improving long-term memory in animals, such as humans, which include R-(-)-amphetamine or a derivative thereof. R-(-)-amphetamine is at least 4 times more effective as a memory enhancer as compared to the commonly prescribed S-(+) enantiomer of amphetamine. In addition, unlike

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S-(+)-amphetamine, the R-(-) enantiomer has not been shown to be addictive (page 26, lines 26-32)¹.” Epstein et al. further discloses that the memory impairment may result from attention deficit disorder (see page 16, lines 6-15).

In light of such a teaching, it would have been *prima facie* obvious to the skilled artisan to modify the composition disclosed by Patrick et al. to include more l-isomer than d-isomer to lessen the addictive side effects of the amphetamine composition and also to improve the efficacy of the composition in treating the symptoms associated with attention deficit disorder.

Furthermore, ADDERALL®, the composition taught by Patrick et al., was known in the art to have a dextroamphetamine:levoamphetamine ratio of 3:1 (see Tulloch et al., p.1406, paragraph bridging col.1 and col.2). Patrick et al. further teaches that compositions containing dextroamphetamine only were also known in the art for the treatment of ADHD (see page 536, col.1-2). While Patrick et al. does not disclose a method of treating attention deficit disorder using two doses wherein the second dose has more l-isomer than d-isomer or is all l-isomer, Epstein et al. provides adequate scientific rationale that one skilled in the art would have been motivated to modify the dextroamphetamine/levoamphetamine composition disclosed in Patrick et al. to administer more l-isomer than d-isomer, or even to administer all l-isomer (see page 26, lines 26-32, where Epstein et al. teaches compositions enriched for one enantiomer), due to the enhanced efficacy and reduction in side effects, such as addiction, associated with the l-isomer. In addition, since each composition was known in the art to be effective for the treatment of attention deficit disorder (see Patrick et al., p.536-538 and Epstein et al., page 16, lines 6-15), it would have been *prima facie* obvious to the skilled artisan to employ a two-pronged regimen, wherein two doses of two separate amphetamine compositions were administered. Motivation to administer two compositions flows logically from the fact that each was known to be administered for the same therapeutic endpoint and it is generally obvious to use in combination two or more agents that have

¹ STN Registry file (Registry No. 156-34-3) is a registry file entry of STN showing that “R-(-)-amphetamine” and

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previously been used separately for the same purpose. Please see *In re Kerkhoven*, 626 F.2d 846, 205 USPQ 1069.

Double Patenting (New Grounds of Rejection)

Obviousness-Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-15 and 22-26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the composition claims of U.S. Patent Nos. 6,605,300; 6,322,819; or 6,913,768, and are provisionally rejected over the composition claims of U.S. Patent Application Nos. 11/091,011; 10/758,417; 10/443,151; 11/030,174 or 11/150,311. This rejection is directed solely to the claims of the above-cited patents that define compositions of matter, i.e., the same statutory category of invention.

Due to the number of applicable different patents and patented claims, a detailed analysis of why the presently claimed subject matter would have been an obvious variation over each one of the

"l-amphetamine" are the same compounds by virtue of their having the same registry number, i.e., "RN".

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applicable claims in different patents is not presented, but the rejection set forth below is applicable to all of the above-cited patents but for differences in claim numbering.

Claims 1-15 and 22-26 are rejected over claims 1-18 of U.S. Patent No. 6,605,300. For the following reasons, the presently claimed subject matter would have been obvious not only over such claims, but over each of the applicable claims of the remaining U.S. Patents or U.S. Patent Applications cited above.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claim is either anticipated by, or would have been obvious over, the reference claims.

Although the conflicting claims are not identical, the claims of the instant application and those of the '300 patent are not considered to be patentably distinct from each other because the patented claims clearly anticipate the present claims. While the claims of the instant application also recite limitations drawn to the release profile of the composition (i.e., more d-amphetamine released earlier in the day than l-amphetamine and more l-amphetamine released later in the day than d-amphetamine), such is not considered to impart any physical or material properties to the composition. In light of such a fact, because the present claims merely require the presence of an effective amount of amphetamine in base and/or salt form, the claims are considered to be anticipated by the '300 patent because the patented claims clearly provide for the active amphetamine component in an effective amount. In addition, the present claims use the word "comprising", which is considered open transitional claim language and allows for the use of other components with the active agent recited in the present claim (see MPEP §2111.03 [R-2] for a discussion of transitional phrases). Thus, the present claims do not patentably exclude the additional components, such as the enteric coatings or carriers of the patented claims. Furthermore, the release characteristics and pharmacokinetic parameters of the composition of the present

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claims and that of the patent are reasonably expected to be same, absent factual evidence to the contrary, since they are comprised of the same chemical entities.

Accordingly, rejection of claims 1-15 and 22-26 of the present application is deemed proper over each of the above-indicated patents as claiming obvious and unpatentable variants.

Claims 16-21 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the method claims of U.S. Patent Application Nos. 11/030,174 or 11/150,311 and is rejected over the method claims of U.S. Patent No. 6,913,768. This rejection is directed solely to the claims of the above-cited patents that define methods of treatment, i.e., the same statutory category of invention.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claim is either anticipated by, or would have been obvious over, the reference claims.

Although the conflicting claims are not identical, the claims of the instant application and those of the copending application or patent are not considered to be patentably distinct from each other because the copending and patented claims clearly anticipate the present claims. The copending or patented claims require the administration of an amphetamine composition for the treatment of attention deficit hyperactivity disorder, which clearly anticipates the present method claims. While the copending claims of U.S. Patent Application No. 11/030,174 and U.S. Patent No. 6,913,768 recite the use of amphetamine compositions with particular mean plasma concentration profiles, such pharmacokinetic properties are considered to be an inherent property of the composition and cannot be separated from the composition itself. Therefore, because the present claims clearly provide for the active amphetamine composition and

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the therapeutic objective of treating ADHD, the method claims of the copending application and patent anticipate the present claims.

Accordingly, rejection of claims 16-21 of the present application is deemed proper over each of the above-indicated copending patent applications as claiming obvious and unpatentable variants.

Conclusion

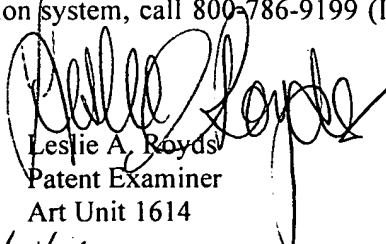
Rejection of claims 1-28 is deemed proper.

No claims of the present application are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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Patent Examiner
Art Unit 1614

October 13, 2006


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